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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/269,897 | 04/02/1999 | KATSUMI AOYAGI | 4047 | 1769 |

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EXAMINER

ZEMAN, ROBERT A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1645

DATE MAILED: 04/09/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/269,897

Applicant(s)

AOYAGI ET AL.

Examiner

Robert A. Zeman

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4, 11, 12, 34, 37, 38 and 41 is/are pending in the application.
- 4a) Of the above claim(s) 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4, 11, 34, 37, 38 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 4, 11, 12, 34, 37, 38 and 41 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16 + 18.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1645

DETAILED ACTION

The amendment and response filed on 1-31-2003 is acknowledged. Claims 9-10, 31-33, 35-36 and 39-40 have been canceled. Claims 4, 11, 34, 37-38 and 41 have been amended. Claims 4, 11, 34, 37-38 and 41 are currently under examination.

This application contains claim 12 drawn to an invention nonelected with traverse in Paper No. 8. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Information Disclosure Statement

The information disclosure statements filed on 9-11-2002 and 2-5-2003 are acknowledged. Initialed copies are attached hereto. However, not all cited references were available. Said references will be considered as they become available.

Claim Objections Withdrawn

The objection to claim 9 for the inadvertent misspelling of the word "genomic" is withdrawn. Cancellation of said claim has rendered the objection moot.

Claim Rejections Withdrawn

The rejection of claims 4, 9-10, 31-36 and 38-40 under 35 U.S.C. 112, first paragraph, as being enabled for methods of treating a sample containing HCV or HBV with a treatment solution but not for a method treating solutions with any virus is withdrawn. Cancellation of

Art Unit: 1645

claims 9-10, 31-33, 35-36 and 39-40 and the amendment to claims 4, 34 and 38 has rendered the rejection moot.

The rejection of claims 4, 9-11, 31-32, 34-37 and 39-40 under 35 U.S.C. 112, first paragraph, as containing subject matter not described in the specification is withdrawn. Cancellation of claims 9-10, 31-32, 35-36 and 39-40 and the amendment to claims 4, 11, 31 and 34 has rendered the rejection moot.

The rejection of claims 10, 36 and 40 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of improper Markush language is withdrawn. Cancellation of said claims has rendered the rejection moot.

The rejection of claims 31-33 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "can readily subjected" is withdrawn. Cancellation of said claims has rendered the rejection moot.

The rejection of claim 31 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "at least 0.1% of". Cancellation of said claim has rendered the rejection moot.

The rejection of claims 31-32 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the terms "at least 0.1% of" and "at least 0.5% of". Cancellation of said claim has rendered the rejection moot.

The rejection of claims 31-32 under 35 U.S.C. 102(b) as being anticipated by Cummins et al. (U.S. Patent 5,081,010) is withdrawn. Cancellation of said claim has rendered the rejection moot.

Art Unit: 1645

Claim Rejections Maintained and New Grounds of Rejection

Claims 4, 11, 34, 37, 38 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sharma (WO 92/19285) in view of Kokai (Japanese Patent Abstract No. 53-104724 – IDS-4) and Cloyd et al. (U.S. Patent 6,074,646) for the reasons outlined in the rejection of claims 4, 9-11 and 31-41 in the previous Office action.

Applicant argues:

1. The specification discloses that the anionic surfactant may adversely affect the probe antibody.
2. The combination of an anionic surfactant and other components like amphoteric surfactants, nonionic surfactants and protein denaturants provides unexpected advantages that virus particles in a sample are efficiently disrupted and the virus antigen is efficiently exposed and released and that an adverse affect of the anionic surfactant on the probe antigen is weakened.
3. Sharma does not suggest or teach the use of the non-surfactant and another surfactant of the instant invention.
4. Sharma does not suggest or teach that the non-ionic surfactant can weaken or inhibit an adverse effect of an anionic surfactant.
5. Kokai does not suggest or teach that the non-ionic surfactant can weaken or inhibit an adverse effect of an anionic surfactant.
6. Cloyd et al. does not refer to the treatment of HCV or HBV.
7. Cloyd et al. disclose that various agents inactivate the viral antigens in the sample since they are non-reactive to HIV-specific antibodies.

Art Unit: 1645

8. Cloyd et al. disclose the use of an immuno precipitation method to detect immune reaction between the HIV and an anti-HIV antibody (i.e. the immune reaction occurs in the absence of the surfactants or other agents).

9. The immune reaction of the instant invention is carried out in the presence of a treatment solution containing the claimed surfactants.

Applicant's arguments have been fully considered and deemed non-persuasive.

Applicant is reminded that the instant claims are drawn to a method of "Treating a hepatitis C (HCV) or hepatitis B virus (HBV) containing sample to obtain a sample suitable for detection of virus by a probe antibody" by treating said sample with a solution containing an anionic surfactant and other components like amphoteric surfactants, nonionic surfactants and protein denaturants.

With regard to Points 1, 2 and 4-5, the effects of the combined components would have the effect of reducing said "adverse effects". The motivation to combine is predicated on increasing the effectiveness of the solution not to reduce said "adverse effects". Moreover, the reduction of said "adverse effects" does not constitute a limitation of the instant claims.

With regard to Points 3 and 6-8, Sharma discloses a composition and method of use for disinfecting blood and discloses that the method is useful for preparation of samples for laboratory testing. Said composition contains at least one non-ionic surfactant and a stabilizer. Sharma differs from the claimed invention in that he does not disclose the use of a combination of surfactants (i.e. non-ionic, anionic and amphoteric). Kokai No. 53-104724 discloses the use of non-ionic surfactants and protein-denaturing agents (urea) for the removal of HBV antigens from blood samples (see 2nd paragraph). Cloyd et al. disclose the treatment of HIV infected sera with a

variety of amphoteric surfactants, non-ionic surfactants, anionic surfactants and protein denaturing agents (see column 19). Additionally, Cloyd et al. disclose that the aforementioned agents inactivated the viral agents in the sample since they were non-reactive HIV-specific (anti-gp120) antibodies. As stated previously, the inability of anti-gp120 antibodies to react with the sample indicates that the virion has been ruptured as indicated by the fact that the envelope protein (gp120) is not intact. Contrary to Applicant's assertion, it does not mean that the samples have been rendered unsuitable for use with an antibody probe. Consequently, it would have been obvious to one of ordinary skill in the art to use the combinations of surfactants disclosed by Cloyd et al. and Kokai No. 53-104724 in the method disclosed by Sharma since the **combinations** of the various surfactants and protein denaturing agents would enhance the effectiveness of Sharma's method of disinfecting samples for use in laboratory tests since their effects would be additive. Moreover, Kokai No. 53-104724 discloses that the use of the disclosed reagents result in a material that can be used as raw material for a vaccine and a standard antigen reagent. Consequently, all the limitations of the instant invention are encompassed by the combination of the cited references. Again, Applicant is reminded that the aforementioned reference is based on the combination of **all** the cited references.

In response to applicant's argument that the references fail to show certain features of applicant's invention (see Point 9), it is noted that the features upon which applicant relies (i.e., the immune reaction is carried out in the presence of a treatment solution containing the claimed surfactants) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 11, 34, 37-38 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of claim 4 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "comprising at least one of urea and an imidazole ring-containing compound or a indole ring containing compound" is maintained. It is unclear what is meant by "one of urea". One molecule? One part? Moreover, it is unclear whether urea is meant to be present in both alternatives or only in the former. The amendment to the said claim was insufficient to overcome the rejection of record.

Claims 11, 37 and 41 are rendered vague and indefinite by method step (2). The wording of said method step is confusing. Moreover, Applicant's reference to the obtained sample being "readily subjected to an immunoassay using an antibody probe" equally confusing since the stated goal of the claimed method is to "obtain a sample suitable for detection of virus by a probe antibody".

Conclusion

No Claim is allowed.

Application/Control Number: 09/269,897
Art Unit: 1645

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Application/Control Number: 09/269,897

Art Unit: 1645

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

NFS
LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Robert A. Zeman
April 1, 2003